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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,754	08/29/2005	Nikola Kirilov Kasabov	PEBL-01001US1 DBB	6902

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EXAMINER

WHALEY, PABLO S

ART UNIT	PAPER NUMBER
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1631

MAIL DATE	DELIVERY MODE
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05/10/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/524,754

Applicant(s)

KASABOV ET AL.

Examiner

Pablo Whaley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 January 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 8-17 is/are pending in the application.
- 4a) Of the above claim(s) 8-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 02/21/2007.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Applicants' response, filed 01/30/2007, has been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied, as necessitated by amendment. They constitute the complete set presently being applied to the instant application.

NON-ELECTED INVENTION

Newly added claims 8-17 are directed to inventions that are independent or distinct from the invention originally claimed for the following reasons: Claims 1-7 are directed to a medical decision support system, method for evaluating a medical decision, and a computer system. Newly added claims 8-17 are directed to a system for predicting a medical outcome that consists of additional distinct components (i.e. layers), and a method for predicting a medical outcome that consists of additional distinct steps of receiving and sorting. Therefore, the inventions of claims 8-17 are distinct as they have different modes of operation and different effects. See MPEP § 806.05(j). Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 8-17 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

CLAIMS UNDER EXAMINATION

Claims 1-6 are herein under examination. Claim 7 has been cancelled.

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PRIORITY

Priority to US Application 60/403,756, filed 08/15/2002, has been acknowledged.

INFORMATION DISCLOSURE STATEMENT

The information disclosure statement filed 02/21/2007 has been considered in full.

NEW MATTER

Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. This is a NEW MATTER rejection.

Claim 1 has been amended to recite "input device". In the response filed 01/30/2007, applicant does not point to support for the newly recited limitation. This limitation is not taught in the specification and is not present within the scope of the original claims as filed. It is noted that the specification discloses input modules, vectors, and signals [p.11, 18, and 22], but does not teach input devices. As the newly recited limitations are not supported by the originally filed claims or disclosure, the claims are rejected for reciting new matter. This rejection is necessitated by amendment.

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CLAIM REJECTIONS - 35 USC § 101

Claims 1-4 were rejected under 35 U.S.C. 101 as being drawn to non-statutory subject matter. Applicant's arguments are persuasive in view of the amendment(s) to instant claims 1 and 3. This rejection is hereby withdrawn.

CLAIM REJECTIONS - 35 USC § 112, 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Amended claims 1, 3, and 5 now recite "to produce a prognosis of an outcome of a disease or its treatment." Due to the use of passive language, it is unclear if this limitation is intended to be an active method step (i.e. producing a prognosis), an intended use, or otherwise. Correction is requested via clearer claim language. This rejection is necessitated by amendment.

CLAIM REJECTIONS - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C.102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 and 5-6 remain rejected and claim 4 is newly rejected under 35 U.S.C. 102 (b) as being unpatentable over Barry et al. (Pat. No. 6,081,786, Issued: Jun. 27, 2000).

This rejection is necessitated by amendment.

Claims 1, 3, and 5 now recite "to produce a prognosis of an outcome of a disease or its treatment." Claim 4 now recites an "evolving fuzzy neural network."

Applicant's arguments, filed 01/30/2007, that Barry et al. do not teach "software to combine...said classified gene expression data or information to produce a prognosis of an outcome of a disease or its treatment" are not deemed to be persuasive. This rejection is maintained for the reasons set forth below.

As set forth in the previous office action mailed 10/19/2006, Barry et al. teach expert systems, methods, and computer program products (i.e. software) for analyzing patient data for guiding the selection of therapeutic treatments for complex disorders. Barry et al. teach multiple inputs for acquiring patient information (i.e. gene expression data) and clinical information (i.e.

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therapy history), as well as an inference engine (i.e. software), and output and memory devices [Fig. 2] and [Fig. 3]. The inference engine (i.e. software) combines data inputs and selects the best treatment for a disease (i.e. prognosis) [Col. 13, lines 21-30] and [Fig. 11D], which the Examiner has broadly and reasonably interpreted as a teaching for the use of said data to “produce a prognosis of an outcome of a disease or its treatment”, as in amended claims 1, 3, and 5. Barry et al. also teach advisory information that can be displayed to a user comprising treatment efficacy and dosages [Col. 5, Table 2] (i.e. prognosis of treatment). Barry et al. teach embodiments of their invention that are entirely hardware (i.e. devices and processors), entirely software, or combination of both software and hardware aspects [Col. 4, ¶ 2]. Thus, the Examiner has reasonably interpreted an “inference engine” to encompass software. Barry et al. also teach inference engines driven by fuzzy logic controlled networks [Col. 8, ¶ 3], as in claim 4. Therefore, for the reasons set forth above and in the previous office action, the Examiner maintains that Barry et al. indeed teach all of the limitations of claims 1-3 and 5-6.

Claims 1-6 remain rejected under 35 U.S.C. 102 (b) as being unpatentable over Slonim et al. (Annual Conference on Research in Computational Molecular Biology, Proceedings of the fourth annual international conference on Computational molecular biology, 2000, p. 263 – 272).

Applicant's arguments, filed 01/30/2007, that Slonim et al. do not teach “software to combine...said classified gene expression data or information to produce a prognosis of an outcome of a disease or its treatment” are not deemed to be persuasive. This rejection is maintained for the reasons set forth below.

As set forth in the previous office action mailed 10/19/2006, Slonim et al. teach a method and computational analysis system for classifying cancer using gene expression data [Abstract].

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Slonim et al. specifically teach "class predictors" as means for suggesting whether a patient would benefit from treatment before actually performing the treatment [p. 264, Col. 1, ¶ 2]. The computational analysis system of Slonim et al. uses a predictive algorithm to compare gene expression and clinical data [p.269, Col. 2, ¶ 1] and displays predictive results that are clearly computer generated [Figs. 3-5]. Therefore, the Examiner maintains Slonim et al. provides implicit teaching for software for combining data, as in claims 1, 3, and 5. Slonim et al. also teaches the use of their class prediction results (based on gene expression and clinical information) as predictors of patient outcomes in response to treatment [p.270, Col. 2, ¶ 2], and prediction results used to direct the treatment of patients [p.268, Section 4], which the Examiner has broadly and reasonably interpreted as teachings for the use of information to "produce a prognosis of an outcome of a disease or its treatment", as in amended claims 1, 3, and 5. Therefore, for the reasons set forth above and in the previous office action, the Examiner maintains that Slonim et al. indeed teach all of the limitations of claims 1-6.

CONCLUSION

No Claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pablo Whaley whose telephone number is (571)272-4425. The examiner can normally be reached on 9:30am - 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached at 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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PRIMARY EXAMINER

